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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/724,409 | 11/28/2000 | Clay B. Siegal | 9632-014 | 9908 |

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EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/28/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/724,409

Applicant(s)
Siegall et al

Examiner
Karen Canella

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20 and 38-62 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-12, 14-20, 38, 42-45, and 50-62 is/are allowed.
- 6) ☒ Claim(s) 13, 39-41, and 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 6) ☐ Other:

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 10, 11, 13, 14, 16-20 have been amended. Claims 38-62 have been added. Claims 10-20 and 38-62 are under consideration.
3. The rejection of claim 10 under 35 U.S.C. 102(b) as being anticipated by any of Tillman et al (J Exp Med, 1992, Vol. 176, pp. 761-779) or Hatano (Accession Number D50136, 1997) or Allesandrini et al (Mol Cell Biol, 1991, Vol. 11, pp. 2096-2107) is withdrawn in light of applicants amendment to the claim.
4. The rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by any of Chen et al (J Biol Chem, 1987, Vol. 262, pp. 13579-13583) or Randen et al (Eur J of Immunol, 1993, Vol. 23, pp. 1220-1225) or Singh et al (Lung Research, 1991, Vol. 17, pp. 59-567) is withdrawn in light of applicants amendment to the claim.
5. The rejection of claims 10-14 and 16-20 under 35 U.S.C. 103(a) as being unpatentable over Braesch-Anderson et al (Journal of Immunological Methods, 1986, vol. 94, pp. 145-151) in view of deBoer (US 5,677,165) is withdrawn.
6. The rejection of claims 10, 11, 13, 14, 16-20 under 35 U.S.C. 103(a) as being unpatentable over Katira et al (Workshop Panel Report in: Schlossman et al, Leukocyte Typing, Vol. V, p. 547) in view of deBoer (US 5,677,165) is withdrawn
7. The rejection of claims 10-20 under 35 U.S.C. 103(a) as being unpatentable over Braesch-Anderson et al (Journal of Immunological Methods, 1986, vol. 94, pp. 145-151) and deBoer (US 5,677,165) as applied to claim 10-14 and 16-20 in section 8 above, and further in view of Francisco et al (Journal of biological chemistry, 1997, vol. 272, pp. 24165-24169) is withdrawn.

8. Applicants arguments regarding the lack of motivation for combining the references based on deBoer is persuasive.

9. Claims 13, 39, 40 and 46-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 and 39-41 are rendered indefinite by recitation of a the Blastp program which is a trade name and thus, an object which is variable.

It is unclear how claim 46 fails to further limit claims 35-45, as the encoded proteins of claim 35-45 are antibody in nature.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 14 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.


Claims 14 and 42 are drawn to isolated nucleic acid which encode proteins which bind to CD40. When given the broadest reasonable interpretation, the claims encompass a genus of nucleic acids which encode a protein which binds to CD40. The specification discloses only an antibody comprising the variable regions of SEQ ID NO:7 and SEQ ID NO:2 which comprises the CDR sequences of SEQ ID NO: 8, 9 and 10. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written

description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties", not a mere wish or plan for obtaining the claimed chemical invention. It is noted that claims 14 and 42 are not defined in terms of nucleic acid sequences, and therefore said claims fails to meet the written description requirement of 35 U.S.C. first paragraph.

12. All other rejections and objections as set forth in Paper No. 6 are withdrawn.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

January 27, 2003